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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,313	07/05/2000	Susan Barnett	PP01631.101	4221

27476 7590 01/23/2009

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/610,313	BARNETT ET AL.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 43-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48-51* is/are allowed.

6)☒ Claim(s) *1-40 and 43-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2008 has been entered.

The amendment filed 10/23/2008 is acknowledged and has been entered.

Claims 1-40, 43-51 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-40 and 43-47 encompass a genus of a polynucleotide sequence encoding an HIV Pol polypeptide wherein the polynucleotide sequence consists essentially of a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32, wherein the genus of polynucleotide sequences is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Pol polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32. The as-filed specification provides sufficient description of an immunogenic HIV Pol polypeptide set forth in SEQ ID NO: 30, 31, or 32. Importantly, the specification does not disclose the structural elements of the Pol polypeptide which are critical for the function of the Pol polypeptide. As such, one of skill in the art would not be able to envisage which variants of SEQ ID NOS: 30-32 which meet the structural limitations of the claims (at least 90% identical to SEQ ID NO: 30, 31 or 32) would result in a polypeptide with the desired function without performing additional experimentation. The genus embraces an indefinite, but potentially very large number of

polynucleotide sequences, considering every possible sequence that is at least 90% identical to SEQ ID NO: 30, 31 or 32. Note: considering that each of SEQ ID NOS 30-31 are at least 2457 nucleotides in length, there are more than 3,662,186,256 different sequences which are 90% to each of SEQ ID NOS: 30-32 (2457*.9=2211, 2457-2211= 246, since there are 4 different possibilities for each individual base difference (i.e., the other three bases and no base), there are 246^4 = 3,662,186,256 distinct sequences which are 90% identical to each of SEQ ID NO: 30-32). The specification does not disclose which nucleotides are considered essential for the function of the encoded pol polypeptide.

The claims recite a structure (polynucleotide encodes an HIV pol polypeptide) which implies that the encoded polypeptide has pol activity, for the genus of polynucleotide sequences. While, one skilled could envision a polynucleotide sequence that is at least 90% identical to the claimed SEQ ID NOs., the skilled artisan would be unable to determine, based on the description in the specification, if the variant sequence would have pol-activity without performing additional experimentation. Thus, the specification does not disclose which polynucleotides with 90% sequence identity to the claimed SEQ ID NOs: 30-32 result in a sequence which encodes a functional HIV-pol and which ones do not.

It is apparent that on the basis of applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of polynucleotide sequences as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of

biochemical or molecular structures of polynucleotide sequences that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient for the specification to merely contemplate a genus of polynucleotide sequences (here, sequences which are at least 90% identical to SEQ ID NO: 30-32) and that have a desired activity (here, HIV Pol activity), without disclosing the structural elements which are critical for the desired activity. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicants' effective filing date. Claiming a genus of polynucleotide sequences that must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of the claimed genus of a polynucleotide sequences that encode an HIV Pol polypeptide that exhibits HIV pol activity; therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one

skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 5-11, and 19-21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 16-22, and 30-32 of U.S. Patent No. 7,211,659 (Application No. 10/190,435). Both sets of claims are directed to an expression cassette comprising a polynucleotide sequence encoding an HIV polypeptide and cells comprising the expression cassette. The polynucleotide sequence SEQ ID NO: 9 in the claims of '659 has at least 90% sequence identity to SEQ ID NO: 30-32 in the instant claims. (99.2% sequence identity with SEQ ID NO: 32). Furthermore, the limitations in instant claims 5-11 and 19-21 are the same as the limitations recited in claims 16-22 and 30-32 of the '659 patent.

Response to Arguments

2. Applicant's arguments filed 10/23/2008 have been fully considered but they are not persuasive.

3. Applicants argue that the rejections should be withdrawn because the claims have been amended to remove the limitation that the HIV Pol polypeptide elicits a Pol-specific immune response and to include the limitation that the polynucleotide sequence consists essentially of a nucleotide sequence having at leas 90% sequence identity to the full of the sequence presented in SEQ ID NO: 30, 31, or 32. This is not persuasive because although the amendment has broadened the scope of the claims, the specification does not provide a disclosure sufficient to describe the genus of molecules encompassed by the claims for the reasons indicated above. Furthermore, the polynucleotide sequence SEQ ID NO: 9 in the claims of '659 has at least 99.2% sequence identity to the instant claimed sequence (SEQ ID NO: 30-32).

4. Therefore, Applicants' arguments are not persuasive.

Allowable Subject Matter

Claims 48-51 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635